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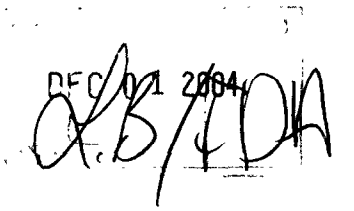

Via Federal Express

Office of Nutritional Products, Labeling,
And Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Re: New Dietary Ingredient Notification: Creatine

Dear Sir or Madam:

Enclosed please find an original and two copies of the 75 day Premarket Notification for the new dietary ingredient creatine from creatine ethyl ester HCl as required by Section 413(a)(2) of the Food, Drug, and Cosmetic Act (FDC Act) and a regulation issued by the Food and Drug Administration (FDA) at 21 CFR Section 190.6

Please note that pursuant to 21 CFR Section 20.61, we request that Attachment 3 product specifications, test methods, test results, and Attachments 24 and 25 ChemPharma Int'l., LLC, final reports identified as Identification and Quantitation of Bioavailable [^{14}C]Compounds Present in the Blood and Urine of Rats Following the Oral Administration of a Single Dose of [^{14}C]Creatine Ethyl Ester and Pharmacokinetics and Identification of [^{14}C]Compounds Present in the Plasma of Rats Following the Oral Administration of a Single Dose of [^{14}C]Creatine from [^{14}C]Creatine Ethyl Ester Hydrochloride be considered confidential information.

Creatine from creatine ethyl ester HCl in powder form will be offered as a new more available source of creatine for dietary supplementation of creatine in the daily diet and to facilitate and maintain muscular health. Creatine is a naturally occurring amino acid in

the bodies of mammals, including humans and animals that is consumed in the human diet. It is a necessary biomolecule for the proper function of skeletal muscle as well as other tissues. When associated with ethanol the two molecules are in the coupled form (ester) or dissociated form – carboxylic acid (i.e. Creatine) and alcohol (i.e. ethanol). The pH of the existing environment determines whether the ester or dissociated form is most prevalent. The submission contains a table of contents that will allow quick reference to the attached documents and scientific studies.

The creatine from creatine ethyl ester HCl that is subject of this 75 day Premarket Notification to FDA is under a license granted by Pro-Nutrient Technologies, Inc. (PNT) to Medical Research Institute. PNT has previously submitted a 75-Day Premarket Notification to FDA for creatine ethyl ester HCl that was dated September 6, 2002. Additionally, we submitted on behalf of Medical Research Institute a 75 day premarket notification for Creatine Ethyl Ester (CE2) on July 16, 2004. FDA safety concerns raised in the PNT and MRI submissions have been addressed in this new 75 Day Premarket Notification for creatine. Within 50 days after receipt of our 75 day premarket notification by FDA, we intend to call the agency to discuss the review status of the notification.

We appreciate your attention to this submission. If you should have any questions regarding the notification, please contact me.

Sincerely,

W. Patrick Noonan

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